IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation, and THE CURATORS OF THE UNIVERSITY OF MISSOURI, a public corporation and body politic of the State of Missouri,	)	
Plaintiffs,	)	C.A. No. 07-551 (GMS) (CONSOLIDATED)
v.	)	
PAR PHARMACEUTICAL, INC., a Delaware corporation,	)	
Defendant.	)	

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

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I. Nature and Stage of The Proceedings

On September 13, 2007, Santarus, Inc. ("Santarus") and The Curators of the University of Missouri ("Missouri") (collectively, "Plaintiffs"), filed this patent infringement suit under the Hatch-Waxman Act against Par Pharmaceutical, Inc. ("Par"). The suit alleges that Par infringed under 35 U.S.C. §271(e)(2) by filing with the FDA an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of Santarus' 20 mg and 40 mg Zegerid® capsule product. Zegerid is the first and only immediate-release oral proton pump inhibitor approved by the FDA. Zegerid comes in several forms, including capsules and powder for oral suspension (which is mixed with water before use). Plaintiffs allege that Par's proposed capsule product infringes U.S. Patent Nos. 6,489,346 (the "'346 patent"); 6,645,988 (the "'988 patent"); and 6,699,885 as reexamined (the "'885 patent").[1] On December 20, 2007, Plaintiffs filed a second patent infringement suit against Par after Par filed a second ANDA seeking approval to market generic versions of Santarus' Zegerid® 20 mg and 40 mg powder for oral suspension product. Plaintiffs allege that Par's proposed powder for oral suspension products infringe U.S. Patent No. 6,780,882 (the "'882 patent), in addition to the '346, '988, and '885 patents (collectively, the "Patents-in-Suit").[2] The Court consolidated these two actions on March 4, 2008.[3]

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1 In October 2, 2007, Plaintiffs filed an amended complaint adding the '885 patent, as reexamined (5894th Reexamination Certificate), to the lawsuit. References herein to the '885 patent claims refer to the claims as set forth in the reexamination certificate. The '346, '885 patent (including its reexamination certificate), and the '988 patent are found in the Joint Appendix ("J.A.") at Tabs 1-3, respectively.

2 In addition, on July 15, 2008, the PTO issued U.S. Patent No. 7,399,772 (the "'772 patent"), which is a continuing application from the '346 patent. (J.A. Tab 5). Prior to issuance of the '772 patent, Plaintiffs informed Par that they wished to include the '772 in this suit, so as to avoid duplicative litigation. On or about July 16, 2008, Plaintiffs listed the '772 patent in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly known as the Orange Book, for Santarus' Zegerid® powder for

Plaintiffs submit this brief in support of their construction of the disputed claim terms of the '346, '988, and '885 patents.[4]

II. Summary of Argument

The parties agree on most claim terms. The parties disagree as to three claim phrases:

1. The phrase "**solid dosage form**" includes a powder that is mixed with water prior to consumption. Dependent claims describe the "solid dosage form" as including "a powder." Additionally, the specification explicitly states that a solid dosage form includes a powder and teaches that it is to be mixed with water when consumed. Par nevertheless asserts that a solid dosage form cannot include powder, but nothing in claims, specification or prosecution history can support Par's construction.

2. The phrase "**at least one optional Secondary Essential Buffer**" means that use of a Secondary Essential Buffer is "optional", *i.e.,* a formulation satisfies the claim (assuming the other elements are met) if it includes such a Secondary Essential Buffer as well as if it does not. The courts have long held that a claim element that is described as "optional" is just that – it is not required. Moreover, in this case the specification could not be clearer or more consistent

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oral suspension 20 mg and 40 mg products, as well as Santarus' 20 mg and 40 mg Zegerid® capsule product. Although Par has yet to serve its Paragraph IV certification with respect to the '772 patent, it has stated to Plaintiffs that it intends to do so in September 2008 and agrees that the '772 patent properly should be included in this litigation. The parties have concluded that their only dispute with respect to construction of the '772 claims relates to the "solid pharmaceutical composition" language that is substantially similar to disputed language in the claims of the other patents, and therefore should be construed consistently with those patents.

[3] Par also filed a counterclaim for declaratory judgment that U.S. Patent 5,840,737 (the "'737 patent") is not infringed, is invalid and unenforceable. Because Plaintiffs have never asserted the '737, and have instead placed it into reissue proceedings, on February 22, 2008, Santarus filed a motion to dismiss the '737 patent from the lawsuit, or in the alternative, stay the case with respect to the '737 patent. That motion is currently pending (D.I. 16).

[4] The parties do not dispute the claim terms found in the '882 patent.

with Plaintiffs' proposed construction, stating directly: "Secondary Essential Buffers are not required in every formulation . . . ." Par's construction seeks to delete the word "optional" from the claims and should be rejected.

3. The phrase "**combining the dosage form ... with an aqueous medium**" includes combining either before or during administration. The plain language of the claim lacks the "prior to administration" limitation Par now seeks to add. Moreover, the specification states that the combining step can be performed either prior to or during administration of the dosage form.

III. Factual Background

The Patents-in-Suit describe and claim, *inter alia,* a drug that is used to effectively treat gastric acid related disorders, such as acid reflux disorder and erosive esophogitis. The drug includes a proton pump inhibitor ("PPI") that helps reduce the amount of acid produced by the cells in the stomach and a buffer to protect PPI from acid degradation in the stomach, thereby allowing for rapid absorption of the PPI. Both Santarus' Zegerid® and Par's proposed generic copy use omeprazole as the PPI and sodium bicarbonate as the buffer.

PPIs suppress stomach acid by blocking the action of acid-producing parietal cells in the lining of the stomach. These parietal cells contain "proton pumps" that release acid into the stomach as part of digestion. When PPI is absorbed into the bloodstream it binds to some of these pumps, blocking the release of acid. Once a pump is blocked by a PPI, it is "turned off" and can no longer release acid for an extended period of time, thereby providing effective treatment.

While PPIs are very effective at blocking acid production, they are themselves extremely sensitive to acid. Unprotected PPIs are quickly destroyed in the stomach's acidic environment and do not survive long enough to be absorbed into the bloodstream where they can work. *See Astra Aktiebolag v. Andrx Pharms., Inc.,* 222 F. Supp. 2d 423, 433-38 (S.D.N.Y. 2003)

(discussing development history and noting "Every formulation scientist or technical witness who testified acknowledged that the task of making a stable omeprazole formulation is quite a challenge."). Astra, the creator of the first PPI, omeprazole, overcame this problem by using an enteric coating, which would not dissolve in the acidic environment of the stomach and would shield the omeprazole from bodily fluids until it reached a non-acidic environment in the small intestine. *Id.* at 435. This led to Astra's successful PPI Prilosec®. Until Santarus introduced Zegerid®, every other oral PPI product on the market relied on an enteric coating approach.

The Patents-in-Suit take a very different approach to successfully delivering omeprazole. The claims at issue are generally directed to a solid dosage form of a PPI combined with a buffer. The claims also require that the solid dosage form is *not* enterically coated. Enteric coatings, by design, delay the release of the PPI. The solid dosage forms of the patents do not have an enteric coating and thus provide for immediate release of the PPI. Once swallowed, the PPI dissolves quickly in the stomach while the buffer protects the PPI from destruction by stomach acid. The result is that the PPI is absorbed more quickly into the bloodstream (as little as 30 minutes versus 90 or more minutes for enterically coated Prilosec). The Patents-in-Suit describe (and claim) the first viable immediate-release PPI formulation.

IV. Legal Standards

The Court is familiar with the standards of claim construction as set forth by the Federal Circuit in cases such as *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) and *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995). Accordingly, Plaintiffs will address specific authorities in the context of discussing the claims at issue and the specific arguments raised.

V. Argument

A. "Solid Dosage Form"

Three of the Patents-in-Suit contain a "solid dosage form" limitation, or variation thereof. These limitations should be all read as including a powder that can be combined with water before being administered to the patient. The claims at issue are claims 24 and 57 of the '346 patent, claim 29 of the '988 patent, and claim 1 of the '885 patent. The claim language and the parties' proposed constructions are set forth below.

Claim Language (disputed language highlighted)	Plaintiffs' Construction of disputed language	Defendant's Construction of disputed language
'346, Claim 24: A method for treating an acid-caused gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject a **solid pharmaceutical composition in a dosage form** that is not enteric-coated; wherein the composition comprises active ingredients consisting essentially of: (a) [omeprazole]; and (b) a buffering agent … wherein the buffering agent is in an amount sufficient to elevate gastric acid pH of the subject's stomach to prevent or inhibit gastric acid degradation of the [omeprazole] and achieve sufficient bioavailability of the [omeprazole] in the subject to elicit a therapeutic effect. '346, Claim 57: A **solid pharmaceutical composition in a dosage form** that is not enteric-coated, comprising: active ingredients consisting essentially of: (a) a therapeutically effective amount of a non-enteric coated [omeprazole]; and (b) a buffering agent….	A solid dosage form that is pharmaceutically acceptable for storage, shipping, and administration, including a powder that can be combined with an aqueous medium and then orally administered	A solid preparation that is administered orally to the subject. Such a preparation would not include powders that are combined with a liquid prior to administration to the subject

Claim Language (disputed language highlighted)	Plaintiffs' Construction of disputed language	Defendant's Construction of disputed language
'988, Claim 29: A **solid oral pharmaceutical dosage form** that is not enteric-coated, comprising: active ingredients consisting essentially of: (a) [omeprazole]; and (b) [buffer]; wherein the dosage form is selected from the group consisting of a suspension tablet, chewable tablet, two-part tablet, effervescent powder, and effervescent tablet.	A solid dosage form that is pharmaceutically acceptable for storage, shipping, and oral administration, including a powder that can be combined with an aqueous medium and then orally administered	A solid preparation that is administered orally to the subject. Such a preparation would not include powders that are combined with a liquid prior to administration to the subject
'885, Claim 1: A method of treating a gastric acid related disorder in a subject in need thereof, comprising: providing a **solid pharmaceutical composition for oral administration** to the subject, the composition consisting essentially of: (a) [omeprazole]; (b) at least one buffering agent…; and (c) one or more optional pharmaceutically acceptable excipients; and orally administering the pharmaceutical composition to the subject ….	A solid dosage form that is pharmaceutically acceptable for storage, shipping, and oral administration, including a powder that can be combined with an aqueous medium and then orally administered	A solid preparation that is administered orally to the subject. Such a preparation would not include powders that are combined with a liquid prior to administration to the subject

1. "solid pharmaceutical composition in a dosage form"

One need look no further than the claims to understand that a "solid pharmaceutical composition in a dosage form" includes a powder. The products at issue here are sold in one of two solid dosage forms: (1) capsules, and (2) a dry powder that is mixed with water to form a suspension and then swallowed by a patient. Par does not contend that capsules are not a "solid" dosage form. Par does, however, seek to exclude powder forms from the claims. Par's argument is that because the patient mixes the powder form with water prior to taking the drug, the powder somehow is not a solid dosage form. This argument is contrary to the plain language of the claims as well as the specification.

The patents at issue all contain claims that clearly demonstrate that a solid dosage form necessarily includes a powder. For example, claim 50 of the '346 patent, which depends from disputed claim 24, specifies that the "dosage form [of claim 24 is] selected from the group consisting of a tablet, ***powder***, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets, and granules." '346 at 42:1-5 (emphasis added) (J.A. at Tab 1). Similarly, claim 81, which depends from disputed claim 57, also explicitly states that the dosage form includes a powder. '346 at 42:23, 43:20. Par's interpretation would render the claims nonsensical, simultaneously requiring and prohibiting a powder. The law prohibits Par's interpretation. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389 (1996) (". . . a term can be defined only in a way that comports with the [patent] as a whole."); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362-63 (Fed. Cir. 2008) (requiring rejection of nonsensical claim interpretations when other reasonable interpretations exist).

The two other patents contain very similar claim language and Par's powder argument suffers from the same infirmity. Claim 3 of the '885 recites: "The method of claim 1 [*i.e.*, "providing a solid pharmaceutical composition for oral administration"], wherein the pharmaceutical composition is in a form selected from the group consisting of a tablet, capsule, ***powder***, suspension tablet . . . ." '885 at 90:31-33 (emphasis added) (J.A. at Tab 2). And in the '988 patent, claim 29 describes a "solid oral pharmaceutical dosage form" … "wherein the dosage form is created by a method comprising: . . . ii) formulating the [omeprazole, buffer and excipient] into a ***powder*** [or] tablet, ..." '988 at 78:25, 30-33 (emphasis added) (J.A. at Tab 3). In this case, one need not even look beyond the plain claim language to know conclusively that a powder is one of the solid dosage forms contemplated by the patent.

If one nevertheless does look beyond the claims themselves, the patent specifications all squarely support Plaintiffs' position that solid dosage forms include a powder: "the ***solid formulation*** of the present invention can be in the form of a ***powder***, a tablet, a capsule, or other suitable solid dosage form . . . ." '346 specification at 16:20-22 (emphasis added); *see also* '346 specification at 11:24-25 ("The inventive composition can alternatively be formulated as a powder, tablet, ..."). The specifications of the '998 and '885 patents contain the same language. '988 at 14:9-11, 8:20-22; '885 at 22:53-55, 8:45-46. Thus, the specification further support the conclusion – mandated by the claim language – that solid dosage forms include powders. *See Phillips*, 415 F.3d at 1316, 1321 (the "specification necessarily informs the proper construction of the claims," and is "the single best guide to the meaning of a disputed term.") (internal citations omitted).

The claims and specifications are also clear that mixing the powder with water before consumption does not change its characterization as a "solid dosage form." The specifications of the '346, '988 and '885 patents provide that the powder is to be mixed with water as part of administration: "the solid formulation of the present invention can be in the form of a powder . . . which creates the inventive solution in the presence of diluent or upon ingestion. . . . [W]ater which is used to swallow the solid dosage form can serve as the aqueous diluent." '346 at 16:20-27; '988 at 14:9-16; '885 at 22:53-60. Notwithstanding the need to take the powder with water, the specifications still refer to it as a "solid" formulation.

Par cannot provide any support for a construction that specifically excludes such powders, because there is none. In fact, the intrinsic evidence that Par cites actually provides further support for Plaintiffs' proposed construction while explicitly contradicting Par's proposed construction. In its portion of the Final Joint Claim Construction Chart (D.I. 32), Par cites the

very language quoted in the preceding paragraph, which refers to a powder that is mixed with water upon administration as a "solid" formulation. Par also cites a sentence from the specification stating: "The pharmaceutical composition is in a solid form prior to dissolution or suspension in an aqueous solution." '346 at 15:9-11. Once again, this text refers to the powder as a "solid form," even while making clear that the "solid form" will be mixed with water prior to consumption. Par's proposed construction also runs contrary to the well established principle that claims should not be construed to exclude a preferred embodiment of the invention. *See, e.g., Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). The patents consistently and repeatedly refer to powder intended to be mixed with water as a "solid" dosage form, and nothing Par cites supports any other view.

Finally, although not precluded by Par's proposed construction, Plaintiffs' construction also clarifies that the solid "dosage form" of the claims is pharmaceutically acceptable for storage, shipping, and administration, as the specifications require. For example, the specifications explain that "it would be advantageous to have a form . . . which can be utilized to instantly make the omeprazole solution/suspension of the present invention which is supplied in a solid form which imparts the advantages of improved shelf-life at room temperature, lower costs to produce, less expensive shipping costs, and which is less expensive to store." '346 at 10:37-43; '988 at 7:36-42; '885 at 7:59-65. The specification also states, "[b]y providing a pharmaceutical composition . . . *in a solid form*, which can be later dissolved or suspended in a prescribed amount of aqueous solution . . . the cost of production, shipping, and storage are greatly reduced as no liquids are shipped (reducing weight and cost), and there is no need to refrigerate the solid form of the composition or the solution." '346 at 15:18-26 (emphasis added); '988 at 13:3-11; '885 at 21:45-53. Thus, the elements of Plaintiffs' proposed

construction regarding the pharmaceutical acceptability for storage, shipping, and administration are clearly supported in the patent.

The Court should reject Par's construction, which would exclude powders that both the claims and the specification expressly state are "solid" dosage forms. Plaintiffs' construction comports with the plain language of the claims.

2. "solid oral pharmaceutical dosage form" and "solid pharmaceutical composition for oral administration"

The proposed constructions for "solid oral pharmaceutical dosage form" and "solid pharmaceutical composition for oral administration," differ from the proposed construction for "solid pharmaceutical composition in a dosage form" in only one way: this language is limited to oral dosage forms, whereas "solid pharmaceutical composition in a dosage form" is not limited only to oral forms.[5] Otherwise, the proposed constructions are the same. The support for these constructions is the same as above. *See, e.g.*, *supra* Part IV.A.1; '988 at 78:9-33, 7:36-55, 8:20-30, 9:40-49, 9:54-10:34, 12:54-62, 13:3-33, 14:9-16; '885 at 7:59-8:11, 8:45-55, 11:66-12:8, 12:12-18, 21:29-22:10, 22:53-60; *see also In re Gabapentin Patent Litig.*, 503 F.3d 1254, 1263 (Fed. Cir. 2007) (courts should give "full meaning to every word of the entire claim term").

[5] This distinction reflects the fact that some examples in the patents contemplate administering the formulation other than orally (*i.e.,* taken through the mouth), such as through a nasogastric tube for critically ill patients unable to swallow. '346 at 7:46-52, 9:5-6; '988 at 4:19-25, 7:51-54; '885 at 4:40-46, 8:8-11.

B. "At Least One Optional Secondary Essential Buffer"

Claim 29 of the '988 patent requires that the solid dosage form consist of a PPI and "at least one Primary Essential Buffer and at least one optional Secondary Essential Buffer."[6] The claim language and the parties' proposed constructions are set forth below.

Claim Language (disputed language highlighted)	Plaintiffs' Construction of disputed language	Defendant's Construction of disputed language
'988, Claim 29: A non-enteric coated solid oral pharmaceutical dosage form, comprising: (a) active ingredients consisting essentially of: (i) a proton pump inhibitor (PPI) … in an amount of approximately 5 mg to approximately 300 mg; and (ii) at least one Primary Essential Buffer and **at least one optional Secondary Essential Buffer** in a total amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor; and (b) a pharmaceutically-acceptable excipient; wherein the dosage form is created by a method comprising: i) blending the proton pump inhibitor, the Primary Essential Buffer, the **optional Secondary Essential Buffer**, and the pharmaceutically-acceptable excipient; and ii) formulating the proton pump inhibitor, the Primary Essential Buffer, the **optional Secondary Essential Buffer**, and the pharmaceutically-acceptable excipient into a powder, tablet, suspension tablet, chewable tablet, capsule, two-part tablet, two-part capsule, effervescent powder, pellet, granule or effervescent tablet.	a buffering agent that is not required in every formulation, but which can be combined with Primary Essential Buffers to produce a higher pH and added neutralization capacity for the formulation	at least one buffer in addition to the recited primary essential buffer, where such additional buffer is unsuitable for use alone because it produces too high a pH value leading to gastrointestinal mucosal irritation

At issue here is whether the term "at least one optional Secondary Essential Buffer" contemplates an "optional" Secondary Essential Buffer or one that is required. In its proposed construction, Par dispenses with the word "optional" outright and asserts that such Secondary

[6] The word "Essential" as used in the claims refers to the amount of buffer required to maintain "Essential pH" in the stomach. '346 at 45:21-22. (J.A. Tab 1).

Essential Buffer is required in all formulations. Par's construction, however, is contrary to the deliberate use of the word "optional" in the claims. It also ignores unequivocal language in the specification stating that Secondary Essential Buffers are ***not required*** in every formulation . . . ." '988 at 45:50-57, 46:51 (emphasis added).

1. The claims themselves establish that a Secondary Essential Buffer is "not required."

The claims themselves establish that the Secondary Essential Buffer is not required. In every instance that the phrase "Secondary Essential Buffer" appears in the claims, it is immediately preceded by the term "optional." *See, e.g.*, claims 25, 26, 27, and 28 (which each state: ". . . wherein the amount of the Primary Essential Buffer and the *optional* Secondary Essential Buffer is effective to . . . .").

Optional means "[l]eft to choice; not compulsory or automatic." American Heritage Dictionary of the English Language (4th ed. 2000). Its well-settled meaning is no different when used in patents. *E.g., Upsher-Smith Labs., Inc., v. Pamlab, L.L.C.*, 412 F.3d 1319, 1332 (Fed. Cir. 2005) (patent application that "optionally includes" antioxidants "teaches vitamin supplement compositions that both do and do not contain antioxidants."); *Civix-DDI, LLC v. Cellco P'ship*, No. 03 C 3792, 2005 WL 831307, at *11 (N.D. Ill. Apr. 6, 2005) (in patent describing "optional code," court concluded that "optional" means "may or may not be included."); M.P.E.P. § 2173.05(h); *Ex Parte Cordova*, 1988 Pat. App. LEXIS 36, at *3-4; 10 U.S.P.Q.2d 1949, 1950, 1952 (Bd. App. & Int. 1988) (claim reciting "and, optionally, an unsaturated aliphatic carboxylic acid" "encompasses a reaction mixture which contains an unsaturated aliphatic carboxylic acid and a reaction mixture which does not contain an unsaturated aliphatic carboxylic acid."); *Ex Parte Wu,* 1988 Pat. App. LEXIS 34, at *92; 10 U.S.P.Q.2d 2031, 2032 (Bd. App. & Int. 1989) (in claim requiring "an epoxy resin, a petroleum

sulfonate and a hydrocarbon diluent optionally containing a polyamine," "[t]he composition set forth in the claim can consist of the first three components recited or it can include a polyamine as a fourth component."). Because the meaning of "optional" is clear, an "optional Secondary Essential Buffer" is not a requirement.

Par seizes on the fact that that the phrase "at least one" precedes "optional" as indicating that the Secondary Essential Buffer is required. Par's argument is flawed for several reasons. First, it simply strikes the word "optional" from the claim, in disregard of ample Federal Circuit precedent that no word in the claims can be rendered surplusage or ignored. *See, e.g.*, *In re Gabapentin*, 503 F.3d at 1263 (courts should give "full meaning to every word of the entire claim term"). *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim."); *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995) ("We must give meaning to all the words in [the] claims.").

Second, only Plaintiffs' construction makes sense of the entire phrase "at least one optional Secondary Essential Buffer." Although linguistically peculiar, the phrase makes sense in the context of a "consisting essentially of" claim such as is at issue here. Unlike traditional open-ended claims marked by a "comprising" transition, claims that use "consisting essentially of" are not open-ended. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Adding further ingredients to a "consisting essentially of" claim can in certain circumstances avoid infringement if they materially affect the basic and novel properties of the invention. *See id.* Thus, expressly reciting "at least one optional Secondary Essential Buffer" is an attempt to make clear that including two (or more) Secondary Essential Buffers does not

avoid infringement. Such a result is consistent with the specification, which contemplates the use of multiple different buffers. *See* Part V.B.2 below.

In short, the Court should adopt Plaintiffs' proposed construction which gives meaning to the entire phrase at issue, and reject Par's construction which simply erases the word "optional" from the claim.

2. The specification makes clear that a Secondary Essential Buffer is "not required"

Were there any doubt about the significance of the word "optional" in the claims, the specification of the '988 patent resolves it. The specification makes perfectly clear that the Secondary Essential Buffer is not required. For example, the invention is summarized as follows: "[t]he present invention provides an oral solution/suspension comprising a proton pump inhibitor and *at least one buffering agent*." '988 at 8:16-18 (emphasis added). The specification leaves no doubt that the invention may include only a single buffer. In describing Essential Buffers, the specification states, "[a]n Essential Buffer may include a buffer or combination of buffers that interact with HCl . . . ." '988 at 45:17-18. It also says that "[e]very formulation is combined with, either directly or indirectly, at least one Primary Essential Buffer," that the Primary Buffer may be used "alone or in combination with Secondary Essential Buffers," and that ***"Secondary Essential Buffers are not required in every formulation . . . ."*** '988 at 45:50-57, 46:51 (emphasis added). The specification also describes "Secondary Components," stating that "[s]econdary components are ***not required*** but may be used to enhance the pharmacological action or as pharmaceutical aids." '988 at 55:51-54 (emphasis added). Secondary Essential Buffers are defined as secondary components. '988 at 56:16-17. Finally, at least thirteen different times the word "buffer(s)" appears in the specification with the "s" in parentheses, indicating that it could be singular and providing further support for the assertion that a single

buffer is sufficient and Secondary Essential Buffers are not required. *See* '988 at 46:2, 46:7, 50:42, 51:3, 51:28, 51:42, 51:57, 52:22, 52:31, 52:46, 52:61, 58:67, 74:51.

The only portion of the specification cited by Par in support of its proposed construction states: "Secondary Essential Buffers neutralize HCl (or other acids in the environment) similarly to the Primary Essential Buffers; however, they produce pH values too high to be used alone, as they would lead to gastrointestinal mucosal irritation." '988 at 46:56-60. This text does absolutely nothing to support Par's proposed construction. It merely describes why the Secondary Essential Buffers cannot be used alone; it does not in any way imply that Secondary Essential Buffers must be used.

3. The prosecution history further supports Plaintiffs' construction

The prosecution history provides further support for Plaintiffs' proposed construction. The word "optional" immediately precedes "Secondary Essential Buffer" countless times, showing that the inventors intended from the start that the Secondary Essential Buffer be optional rather than required. *See, e.g.*, '988 File History July 11, 2002 Response at 2, 5, 6, 16, 18 (J.A., Tab 11); Dec. 2, 2002 Response at 10, 13, 14 (J.A. Tab 13); Dec. 18, 2002 Supplemental Amendment at 2, 3 (J.A. Tab 14). Initially the "Secondary Essential Buffer" was recited only in a dependent claim, and thus clearly was not required to satisfy the independent claim. '988 File History, July 9, 2001 original application, p. 123 (J.A. Tab 9). Later, "Secondary Essential Buffer" was added to the independent claim but only (and always) preceded by the word "optional" to preserve the fact that it is not required. '988 File History, July 11, 2002, Response at 2 (J.A. Tab 11). Finally, *after* the patentee had overcome all outstanding prior art rejections, it added "at least one" resulting in the "at least one optional" language in the final claims. '988 File History, September 25, 2002, Office Action at 2. (J.A. Tab 12). As discussed above, this is easily understood as a way of clarifying that the otherwise

closed claim does not exclude a formulation with more than one Secondary Essential Buffer. Nothing in the prosecution history detracts from the deliberate use of the word "optional" as indicating, consistent with the specification, that "Secondary Essential Buffers are not required in every formulation . . . ." '988 at 45:56.

The three passages from two of patentee's Office Action Responses cited by Par in the Final Joint Claim Construction Chart (D.I. 32) do not dictate otherwise. First, Par cites to the July 11, 2002 Office Action Response. There, the applicant wrote, "The claims have been amended to better define the invention. In particular, the nonenteric coated or non-delayed-release pharmaceutical dosage form comprises active ingredients consisting essentially of a non-enteric coated proton pump inhibitor, a Primary Essential Buffer, and a Secondary Essential Buffer." '988 File History, July 11, 2002 Response at 11, 12 (J.A. Tab 11). Presumably Par will assert that these lines support its proposed construction because the word "optional" is not used there. However, it is clear that the above passage is simply intended to highlight the recited active ingredients in a shorthand form, not to recapitulate the entire claim. Notably, at this point in the prosecution, the "at least one" language had not yet been added, and the claims recited only an "optional" Secondary Essential Buffer. Moreover, at least thirteen times within the same Response the word "optional" is used to describe the "Secondary Essential Buffers," including on a page to which Par cites in support of its construction. *See id.* at 18 ("an optional Secondary Essential Buffer"); *see also id.* at 2, 5, 6, 16 (using the word "optional" with "Secondary Essential Buffer"). The Federal Circuit has made clear that such at best ambiguous comments by an applicant cannot be used to undercut the express language of the claims. *See Phillips.*, 415 F.3d at 1317 (Fed. Cir. 2005) (en banc) ("because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation,

it often lacks the clarity of the specification and thus is less useful for claim construction purposes."). That applicant failed to use the word "optional" in one sentence in its remarks – while describing the Secondary Essential Buffer as "optional" in at least thirteen other places in the same paper, including the claims – is hardly the sort of "clear and unambiguous disavowal" that would be required to strip the word "optional" from the claims as Par now urges. *See, e.g., Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 833 (Fed. Cir. 2003) ("We therefore do not consider the applicants' statement to be a clear and unambiguous disavowal of claim scope as required to depart from the meaning of the term . . . .").

Par also cites in the Final Joint Claim Construction Chart to the December 2, 2002 Office Action Response. Shown there is the amendment to claim 1 which changes the wording "an optional Secondary Essential Buffer" to "at least one optional Secondary Essential Buffer." '988 File History Dec. 2, 2002 Response at 10 (J.A. Tab 13). Presumably, Par believes that because "at least one" was added to the language, the applicant intended to eliminate the optional nature of the Secondary Essential Buffer. However, the word "optional" was not removed. If the applicant had intended to make the Secondary Essential Buffer mandatory by adding the phrase "at least one," it would have manifested that intention by deleting the word "optional." But it did not.. The applicant affirmatively chose to keep the word "optional" because it clearly intended for the Secondary Essential Buffer to remain optional, as evidenced by amended claim 6 in the same response. *See id.* Claim 6, which depends from claim 1, recites the following: "The dosage form of claim 1, wherein the amount of the Primary Essential Buffer and the *optional* Secondary Essential Buffer is effective to elevate the pH . . . ." *Id.* (emphasis added). Thus, dependent claim 6 makes perfectly clear that even though "at least one" was added to claim 1, the word "optional" was purposefully left in the claim, and the Secondary Essential Buffer never

became a required part of the formulation. Once again, in the same Response there are numerous other references to the optional nature of the Secondary Essential Buffer. *See id.* at 13, 14.

In sum, Par's bold request that the Court delete the word "optional" from the claims should be rejected. The claims and specification make abundantly clear that Secondary Essential Buffers are not required, and the prosecution history compels the same conclusion.

C. "Combining the Dosage Form of Claim 57 With an Aqueous Medium" ['346 patent claim 90]

Claim 90 of the '346 patent contains the limitation that the solid dosage form of independent claim 57 is combined with an aqueous medium. The claim language and the parties' proposed constructions are set forth below.

Claim Language (disputed language highlighted)	Plaintiffs' Construction of disputed language	Par's Construction of disputed language
'346 Claim 90: A method of producing a liquid pharmaceutical composition comprising: **combining the dosage form of claim 57 with an aqueous medium.** Claim 57 states: A solid pharmaceutical composition in a dosage form that is not enteric-coated, comprising: active ingredients consisting essentially of: (a) a therapeutically effective amount of [PPI]; and (b) a [buffer].	requires combination with a medium that includes water	requires combination with an aqueous medium prior to oral administration to the subject

The parties' constructions are the same, with the exception that Par's construction requires combining the solid dosage form in an aqueous medium prior to oral administration, a requirement not supported by the claim or the specification. Plaintiffs' construction of this term, on the other hand, is consistent with both the disclosure of the patent specification and the plain meaning of the terms as understood by one skilled in the art. The '346 patent clearly states that the inventive aqueous combination can be formed before or during ingestion: "the solid formulation of the present invention can be in the form of a powder, a tablet, a capsule, or other

suitable solid dosage form . . . which creates the inventive solution in the presence of diluent or upon ingestion. For example, the *water in the stomach secretions or water which is used to swallow the solid dosage* form can serve as the aqueous diluent." '346 at 16: 21-28 (emphasis added).

Moreover, the differences between various claims are "a useful guide in understanding the meaning of particular claim terms." *See Phillips*, 415 F.3d at 1314. In this case, claim 94 of the '346 patent specifically recites a method for administering a liquid pharmaceutical composition comprising "combining the pharmaceutical composition . . . with an aqueous medium to form a suspension, and orally administering the suspension to the subject." '346 at 16: 21-28. The differences between claim 94 and claim 90 demonstrate that the inventor viewed combining first and then orally administering as different from simply "combining." Indeed, under Par's construction claim 94 simply would be superfluous. *See Clearstream Wastewater Sys. Inc. v. Hydro-Action Inc.*, 206 F.3d 1440, 1446 (Fed. Cir. 2000) ("Under the doctrine of claim differentiation, it is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims. . . . [I]t prevents the narrowing of broad claims by reading into them the limitations of narrower claims.").

Finally, one skilled in the art would understand that the water-based secretions of the stomach constitute an "aqueous medium" based on the plain meaning of the claim. The plain meaning of "aqueous" is "relating to, similar to, containing, or dissolved in water; watery." *The American Heritage Dictionary* (3d ed. 1985). Thus, combining a dosage form with the water-containing secretions of the stomach falls squarely within the plain language of the claim.

In contrast, Par's proposed construction runs counter to both the plain meaning of the claim and the teaching of the specification. Par's construction attempts to limit the claim to a

single embodiment—a liquid formed before administration—despite the clear teaching of the '346 patent. "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (2004). Here, of course, the patentee both discloses multiple embodiments in the specification ('346 at 16:21-28) and demonstrates a clear intent *not* to limit claim 90 to a single embodiment. *Cf.* Claim 94. Thus, Par's construction cannot be correct.

VI. Conclusion

For the reasons discussed above, Plaintiffs submit that their constructions of the claim terms at issue are fully supported by both the intrinsic and extrinsic evidence. Plaintiffs respectfully request that the Court adopt Plaintiffs' construction of these terms.

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CERTIFICATE OF SERVICE

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